INSTRUCTIONS FOR USE

Presillion™ plus CoCr Coronary Stent on RX System

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STERILE. Sterilized with ethylene oxide gas

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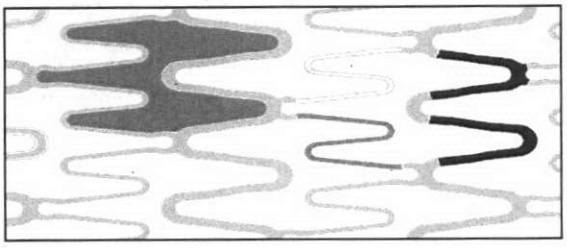
1. Device Description

Presillion™ *plus* CoCr Coronary Stent on RX System includes a balloon expandable intracoronary L-605 Cobalt Chromium (CoCr) Presillion stent, premounted on a rapid exchange balloon catheter (the Delivery System).

The Presillion stent is cut from panels of flat sheets of L-605 cobalt chromium alloy. First the pattern is cut from panels of flat sheet; then the stents are folded into cylinders and welded. The Presillion stent geometry is a continuous "closed cell" design, with adaptive cells capable of differential lengthening. This enables the stent to be flexible in the unexpanded configuration and to support the vessel, while conforming to its curvature, in the expanded configuration.

Figure 1: Stent Design



Green background – Closed cell
Red – Wide struts
Orange & Yellow – Thin struts

At the distal end of the catheter is a delivery balloon. The balloon is designed to expand to a controlled diameter and length when inflated. The balloon delivery catheter has two platinum iridium radiopaque marker bands defining the length and location of the mounted stent.

The usable length of the delivery system is 135cm with a shaft profile of 1.9F (64mm) / 2.8F (.94mm) (proximal/distal). The catheter has a distal port (hole) approximately 25cm from the distal tip that accesses the guidewire lumen. The guidewire lumen begins at the distal port and terminates at the distal tip. The catheter also has two (2) markers on the proximal catheter shaft that indicate, approximately, the exit of the balloon catheter tip from the guiding catheter (brachial: 90cm; femoral: 100cm).

Table 1: Presillion *plus* Stent System Specifications

STENT INNER DIAMETER (MM)	STENT LENGTH (MM)	MINIMUM GUIDING CATHETER COMPATIBILITY (ID)	STENT NOMINAL PRESSURE (ATM)	RATED BURST PRESSURE-RBP (ATM)	STENT FREE AREA (%)
2.50	8,12,17,20	5F (0.056")	12	18	89.2
2.75 – 3.00	8,12,17,20,24,28,33	5F (0.056")	12	18	86.9
3.50, 4.00	8,12,17,20,24,28,33	5F (0.056")	12	18	86.5

Table 2: Presillion *plus* Stent System Crossing Profiles

SYSTEM LABELED DIAMETER (MM)	SYSTEM LABELED LENGTH (MM)	CROSSING PROFILE (AVERAGE)
2.50	8, 12, 17, 20	1.01
2.75	8	1.09
2.75	12, 17, 20, 24, 28, 33	1.07
3.00	8, 12, 17, 20, 24, 28, 33	1.11
3.50	8, 12, 17, 20, 24, 28, 33	1.20
4.00	8	1.28
4.00	12, 17, 20, 24, 28, 33	1.27

2. Indications for Use

Presillion™ *plus* CoCr Coronary Stent on RX System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease associated with stenotic lesions in de novo native coronary arteries (length ≤ 30mm) with a reference vessel diameter of 2.50mm to 4.00mm.

3. Contraindications

Coronary artery stenting is generally contraindicated in the following patient types:

- Patients for whom antiplatelet and/or anticoagulation therapy is contraindicated
- Patients judged to have a lesion which prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery system

4. Warnings

- Since the use of this device carries the associated risks of thrombosis, vascular complications, and/or bleeding events, judicious selection of patients is necessary.
- Persons allergic to L-605 cobalt chromium alloy may suffer an allergic response to this implant.

5. Precautions

See also section 8.1 *Individualization of Treatment.*

- Do not use with Ethiodol or Lipiodol contrast media*.
- Do not expose the delivery system to organic solvents such as alcohol or detergents.
- Only physicians who have received appropriate training in interventional procedures should perform implantation of the stent.
- Stent placement should be performed only at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized coronary stents is not well characterized.

* Ethiodol and Lipiodol are trademarks of Guebet S.A

- When multiple stents are required, stent materials should be of similar composition. Placing multiple stents of different materials in contact with each other may increase the potential for corrosion.
- The device should be manipulated while under high-quality fluoroscopic observation.
- Do not advance or retract the catheter unless the balloon is fully deflated. If resistance is met during manipulation, determine the cause of resistance under fluoroscopy before proceeding.
- Do not try to straighten a kinked hypotube. Straightening a kinked metal shaft may result in breakage of the shaft.

5.1 Use in Special Populations

The safety and effectiveness of Presillion™ *plus* CoCr Coronary Stent on RX System has not been established in the following patient populations:

- Patients with presence of definite or probable intra-luminal thrombus
- Patients with coronary artery reference vessel diameter < 2.5mm or > 4.0mm
- Patients with lesions longer than 30 mm
- Patients with unprotected lesions located in the left main coronary artery
- Patients with tortuous vessels that may impair stent placement in the region of the obstruction or proximal to the lesion
- Patients with moderate or severe lesion calcification
- Patients with poor flow in the target vessel
- Patients with multi-vessel disease
- Patients with in-stent restenosis
- Patients with chronic total occlusions
- Patients with ostial lesions
- Patients with bifurcation lesions
- Patients with longer than 12 months follow-up

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser angioplasty catheters, in conjunction with the Presillion *plus* Stent System, have not been established.

5.2 Stent and Delivery System Handling – Precautions

- **For single use only**. Do not re-sterilize or reuse. Do not use the device if the package is opened or damaged.
- Note the product "Use By" date.
- Do not remove the stent from its stent delivery system as removal may damage the stent and/or lead to stent embolization. Presillion *plus* Stent System is intended to perform as a system. The Presillion stent is not designed to be manually re-crimped onto another delivery device.
- Do not use the stent delivery system in conjunction with any other stents.
- Take special care not to handle or in any way disrupt the stent on the balloon. This is most important during removal of the catheter from the packaging, placement over the guidewire, and advancement through the large-bore rotating hemostatic valve and guiding catheter hub.
- Do not manipulate the stent. Manipulation, e.g. rolling the mounted stent with your fingers, may loosen the stent from the delivery system balloon and cause dislodgment.

- Take care when inserting the delivery system into the hemostasis valve in order to avoid kinking.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon.
- When back loading the catheter on the guidewire, provide adequate support to shaft segments.

5.3 Stent Placement – Precautions

- Do not induce a vacuum on the delivery system before reaching the target lesion.
- Do not prepare or pre-inflate the stent delivery system prior to placement of the stent across the lesion. Use the balloon purging technique described in Section 10 of the Operator's Manual.
- Implanting a stent may lead to a dissection of the vessel distal and/or proximal to the stented portion and may cause acute closure of the vessel, requiring additional intervention (CABG, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be stented first, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chances for dislodgment.
- Do not expand the stent if it is not properly positioned in the vessel.
- Placement of the stent has the potential to compromise side branch patency.
- Do not exceed rated burst pressure as indicated on the product label as this may result in a ruptured balloon, with possible intimal damage and dissection.
- Should any resistance be felt at any time during either lesion access or removal of the stent delivery system pre-stent implantation, the system should be removed per instructions in section 5.4 *Stent/System Removal - Precautions*.
- Stent retrieval methods (use of additional wires, snares, and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications may include bleeding, hematoma, pseudoaneurysm, or vessel perforation.
- Guiding catheters used must have lumen sizes that are suitable to accommodate the introduction of the 2.8F Stent Delivery System. Refer to table 1 for recommended guiding catheter.
- Do not induce a negative pressure on the delivery catheter prior to placement of the stent across the lesion. This may cause premature dislodgment of the stent from the balloon.

5.4 Stent/System Removal – Precautions

Should **unusual** resistance be felt at **any time** during either lesion access or removal of the stent delivery system pre-stent implantation, the entire system must be removed as a single unit.

When removing the delivery system as a single unit, proceed as follows:

1. **DO NOT** retract the delivery system into the guiding catheter.
2. Position the proximal balloon marker distal to the tip of the guiding catheter.
3. Advance the guidewire into the coronary anatomy as far distally as safely possible.
4. Tighten the rotating hemostatic valve to secure the stent delivery system to the guiding catheter.
5. Remove the guiding catheter and stent delivery system as a **single unit**.

Failure to follow these steps and/or the application of excessive force to the stent delivery system can potentially result in loss or damage to the stent and/or stent delivery system components.

5.5 Post Implant - Precautions

Great care must be exercised when crossing a newly deployed stent with other devices, such as another stent delivery system, an intravascular ultrasound (IVUS) catheter, a coronary guidewire, or balloon catheter, to avoid disrupting the stent geometry.

MR Conditional

5.5.1 MRI Information

Non-clinical testing has demonstrated the Presillion Stent, in single and overlapped configurations up to 73mm of length, is MR Conditional. It can be scanned safely; immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3 Tesla
- Maximum spatial gradient magnetic field of 1100 Gauss/cm or less
- Maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg or less with the MR system operating in the Normal Operating Mode for 15 minutes of scanning (per pulse sequence)

Additional MRI Heating Information

Stent heating was derived by using the measured non-clinical, in vitro temperature rises in a GE Excite 3 Tesla scanner and in a Siemens Magnetom 1.5 Tesla coil in combination with the whole body averaged specific absorption rates (SARs) in the ASTM phantom. At overlapped lengths of up to 73mm, the Presillion stent produced a nonclinical maximum local temperature rise of 2.5°C scaled to a maximum whole body averaged SAR of 2.0 W/kg (normal operating mode) for one sequence of 15 minutes. These calculations do not take into consideration the cooling effects of blood flow.

Image Artifact Information

The calculated image artifact extends approximately 4.7mm from the perimeter of the device diameter and 1mm beyond each end of the length of the stent when scanned in non-clinical testing using a Spin Echo sequence. With a Gradient Echo sequence, the calculated image artifact extends 7.4mm beyond the perimeter of the diameter and 3mm beyond each end of the length, with both sequences partially shielding the lumen; measurements performed in a 3.0 Tesla Magnetom Trio, Siemens Medical Solutions, software version Numaris/4, syngo MR 2004A 4VA25A, actively shielded MR system.

Medical Registration

It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

6. Adverse Events

6.1 Observed Adverse Events

The principal adverse event experience with the Presillion™ *plus* CoCr Coronary Stent on RX System is derived from the PIONIR study. This study was a comparison of the Presillion stent to a performance goal (PG) derived from literature on other approved coronary stents.

Table 3: In and Out of Hospital Complications through 360 days
% (Number/Denominator) [95% Confidence Interval]

SAFETY MEASURES	IN HOSPITAL COMPLICATIONS	COMBINED IN AND OUT OF HOSPITAL COMPLICATIONS TO 30 DAYS	COMBINED IN AND OUT OF HOSPITAL COMPLICATIONS TO 180 DAYS	COMBINED IN AND OUT OF HOSPITAL COMPLICATIONS TO 270 DAYS	COMBINED IN AND OUT OF HOSPITAL COMPLICATIONS TO 360 DAYS
TVF[1] (Cardiac death, Target Vessel MI, Clinically driven TVR[2])	2.2% (6/278) [0.8%, 4.6%]	2.5% (7/277) [1.0%, 5.1%]	4.7% (13/277) [2.5%, 7.9%]	8.7% (24/276) [5.7%, 12.7%]	10.3 (28/273) [6.9%, 14.5%]
All Death	0.4% (1/278) [0.0%, 2.0%]	0.4% (1/277) [0.0%, 2.0%]	1.1% (3/277) [0.2%, 3.1%]	1.4% (4/276) [0.4%, 3.7%]	1.5% (4/273) [0.4%, 3.7%]
o Cardiac Death	0.4% (1/278) [0.0%, 2.0%]	0.4% (1/277) [0.0%, 2.0%]	0.7% (2/277) [0.1%, 2.6%]	1.1% (3/276) [0.2%, 3.1%]	1.1% (3/273) [0.2%, 3.2%]
o Non cardiac Death	0.0% (0/278) [0.0%, 1.3%]	0.0% (0/277) [0.0%, 1.3%]	0.4% (1/277) [0.0%, 2.0%]	0.4% (1/276) [0.0%, 2.0%]	0.4% (1/273) [0.0%, 2.0%]
Target Vessel MI	2.2% (6/278) [0.8%, 4.6%]	2.5% (7/277) [1.0%, 5.1%]	2.9% (8/277) [1.3%, 5.6%]	3.3% (9/276) [1.5%, 6.1%]	3.3% (9/273) [1.5%, 6.2%]
o Q Wave MI[3]	0.7% (2/278) [0.1%, 2.6%]	0.7% (2/277) [0.1%, 2.6%]	0.7% (2/277) [0.1%, 2.6%]	0.7% (2/276) [0.1%, 2.6%]	0.7% (2/273) [0.1%, 2.6%
o Non-Q Wave MI[4]	1.4% (4/278) [0.4%, 3.6%]	1.8% (5/277) [0.6%, 4.2%]	2.2% (6/277) [0.8%, 4.7%]	2.5% (7/276) [1.0%, 5.2%]	2.6% (7/273) [1.0%, 5.2%]
Clinically Driven TVR	0.7% (2/278) [0.1%, 2.6%]	1.1% (3/277) [0.2%, 3.1%]	2.9% (8/277) [1.3%, 5.6%]	6.5% (18/276) [3.9%, 10.1%]	8.1% (22/273) [5.1%, 11.9%]
Clinically Driven TLR[5]	0.7% (2/278) [0.1%, 2.6%]	1.1% (3/277) [0.2%, 3.1%]	2.5% (7/277) [1.0%, 5.1%]	5.1% (14/276) [2.8%, 8.4%]	6.2% (17/273) [3.7%, 9.8%]
Stent Thrombosis[6] (Definite, Probable)	0.7% (2/278) [0.1%, 2.6%]	1.1% (3/277) [0.2%, 3.1%]	1.1% (3/277) [0.2%, 3.1%]	1.1% (3/276) [0.2%, 3.1%]	1.1% (3/273) [0.2%, 3.2%]
Bleeding complications[7]	0.0% (0/278) [0.0%, 1.3%]	0.7% (2/277) [0.1%, 2.6%]	0.7% (2/277) [0.1%, 2.6%]	1.1% (3/276) [0.2%, 3.1%]	1.1% (3/273) [0.2%, 3.2%]
Vascular complications[8]	1.4% (4/278) [0.4%, 3.6%]	1.8% (5/277) [0.6%, 4.2%]	1.8% (5/277) [0.6%, 4.2%]	1.8% (5/276) [0.6%, 4.2%]	1.8% (5/273) [0.6%, 4.2%]

[1] Target Vessel Failure – Cardiac death, target vessel myocardial infarction (Q Wave and non-Q-wave), or clinically driven target vessel revascularization (TVR) by percutaneous or surgical methods.

[2] Target Vessel Revascularization–Any percutaneous intervention of surgical bypass of any segment of the target vessel.

[3] Q wave MI (QWMI) - Requires one of the following criteria:

- Chest pain or other acute symptoms consistent with myocardial ischemia and new pathological Q waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC, in the absence of timely cardiac enzyme data.
- New pathologic Q waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC and elevation of cardiac enzymes. In the absence of ECG data the CEC may adjudicate Q wave MI based on the clinical scenario and appropriate cardiac enzyme data.

[4] Non Q-Wave MI - Elevation of CK levels to > 2.0 times normal with elevated CK-MB in the absence of new pathological Q waves (WHO definition).

[5] Target Lesion Revascularization – Any percutaneous intervention of the target lesion or bypass surgery of the target vessel performed for restenosis or other complication of the target lesion.

[6] Stent Thrombosis (ARC)–Thrombus or closure within the stented vessel. Acute (0–24 hours post stent implantation), Subacute (>24 hours–30 days post stent implantation), or late (30 days – 1 year post stent implantation).

[7] Bleeding complication – A procedure-related hemorrhagic event that requires a transfusion and/or surgical intervention.

[8] Vascular complication– May include the following: Pseudoaneurysm, Arteriovenous fistula (AVF), Peripheral ischemia/nerve injury, Vascular event requiring transfusion or surgical repair.

6.2 Potential Adverse Events

Adverse events (alphabetical order) that may be associated with the implantation of a coronary stent in coronary arteries include, but are not limited to:

- Abrupt vessel closure
- Allergic reaction
- Aneurysm
- Arrhythmias
- Cardiac tamponade
- Coronary artery spasm
- Death
- Dissection
- Drug reactions to antiplatelet agents / anticoagulation agents / contrast media
- Emboli, distal (tissue, air or thrombotic emboli)
- Emergency CABG
- Failure to deliver the stent to the intended site
- Fever
- Fistulization
- Hemorrhage or hematoma
- Hypotension / Hypertension
- Infection and pain at the insertion site
- Myocardial infarction
- Myocardial ischemia
- Occlusion
- Perforation
- Prolonged angina
- Pseudoaneurysm
- Renal failure
- Repeat percutaneous intervention
- Restenosis of stented segment (greater than 50% obstruction)
- Rupture of native and bypass graft
- Stent compression
- Stent misplacement / migration / embolization
- Stroke
- Thrombosis (acute, sub-acute or late)
- Stable or Unstable angina
- Ventricular fibrillation
- Vessel spasm

7. Clinical Data

The PIONIR™ clinical study was the pivotal study conducted to demonstrate the safety and effectiveness of the Presillion™ *plus* CoCr Coronary Stent on RX System . As the Presillion™ *plus* CoCr Coronary Stent on RX System represents minor modifications to the Presillion™ Stent System (the stent is identical in both systems), two additional clinical studies are applicable and considered supportive studies of the Presillion™ *plus* CoCr Coronary Stent on RX System :

- The control arm from the BLAST study – a phase II, randomized, double blind clinical study of the Presillion Stent System in combination with Liposomal Alendronate, compared to the Presillion Stent System alone, in treatment of de novo stenotic lesions in native coronary arteries in a population undergoing PCI.
- The Belgian Registry – a single arm registry, evaluating the safety of Presillion Stent System in the treatment of de novo stenotic lesions in native coronary arteries.

7.1 PIONIR Study – Presillion™ and Presillion™ *plus* CoCr Coronary Stent on RX Systems

7.1.1 Study Overview

The PIONIR was a non-randomized, multi-center, prospective, single arm clinical study conducted in Germany, Sweden, Belgium and Israel.

The main objective of this study is to evaluate the safety and effectiveness of Presillion™/ Presillion™ *plus* CoCr Coronary Stent on RX System in the treatment of patients with symptomatic ischemic heart disease with single de novo stenotic lesions in native coronary arteries with length ≤ 30mm and a reference vessel diameter of 2.50mm to 4.00mm. The intention was to cover the index lesion with one stent of adequate length. For bailout procedures or in the event of a sub-optimal result, further stenting was employed, at investigator's discretion, using the Presillion™/ Presillion™ *plus* CoCr Coronary Stent on RX Systems , as required. Given the similarities between the Presillion and Presillion™ *plus* CoCr Coronary Stent on RX Systems , either could be used in this study.

The primary endpoint is the incidence of target vessel failure (TVF - cardiac death, target vessel myocardial infarction (MI [Q wave or non-Q wave]), or clinically driven target vessel revascularization (TVR) by percutaneous or surgical methods) within 270 days of treatment with the Presillion™/ Presillion™ *plus* CoCr Coronary Stent on RX System . This rate is compared with a performance goal derived using a meta-analysis of literature articles reporting outcomes with approved bare metal coronary stents.

Secondary clinical endpoints include the following:

1. All Death at 30, 180, 270, and 360 days
2. Cardiac Death at 30, 180, 270, and 360 days
3. MI at 30, 180, 270, and 360 days
4. Clinically driven Target Lesion Revascularization (TLR) at 30, 180, 270, and 360 days
5. TVR at 30, 180, 270, and 360 days
6. Acute Success Rates
   a. Device Success: Attainment of < 50% final residual stenosis of the target lesion using only Presillion™ or Presillion™ *plus* Stent Systems
   b. Lesion Success: Attainment of < 50% final residual stenosis of the target lesion using any percutaneous method
   c. Procedure Success: Attainment of < 50% residual stenosis of the target lesion and no in-hospital death, MI, or TLR
7. Bleeding or Vascular Complications at hospital discharge

8. Stent Thrombosis at hospital discharge at 30, 180, 270, and 360 days

Summary of the PIONIR™ Study

Study Type	• Multi-center study (n=16), performed in Europe (Germany, Sweden and Belgium) and Israel. • Prospective single arm • Patients can be treated with the Presillion™ or Presillion™ *plus* CoCr Coronary Stent on RX Systems , as available
Number of patients	278
Lesion criteria	Single de novo stenotic lesions in native coronary arteries (length ≤ 30 mm) with a reference vessel diameter of 2.50mm to 4.00mm
Stent sizes (mm)	• Diameter 2.5; Lengths: 8, 12, 17, 20 • Diameters: 2.75, 3.0, 3,5, 4.0; Lengths: 8, 12, 17, 20, 24, 33
Anti-platelet therapy	• Aspirin, indefinitely • Clopidogrel, Prasugrel, or Ticlopidine, for a minimum of 1 month post procedure
Follow up	At: discharge, 30 days, 180 days, 270 days, and 1 year
Sponsor	Medinol Ltd.

7.1.2 Patient Characteristics

	% of Number of patients (N = 278)
Age (years)	65.5±10.6
Male	76.3%
Current smokers	23.7%
Hypercholesterolemia	76.2%
Hypertension	72.3 %
Previous MI	27.8%
Diabetes • Diet controlled • Oral Hypoglycemics • Insulin	20.5% 4.0% 12.2% 4.3%

7.1.3 Adverse Events

An independent Clinical Events Committee adjudicated all clinical endpoint events in this study.

7.1.4 Effectiveness and Safety - Results

The 270-day TVF rate was 8.7% and the upper bound of the exact one-sided 95% confidence interval was 12.7%. Since this upper bound is less than the established performance goal of 16.46%, the performance goal is considered to have been met.

The 270-day TLF rate was 7.6% (21/276). Lesion success[1] was achieved in 100.0% (281/281) of cases; device success[2] was achieved in 98.2% (276/281) of cases; and procedural success[3] was achieved in 97.8% (272/278) of cases.

Table 4 below displays the principal effectiveness and safety results.

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[1] Lesion success - attainment of <50% final residual stenosis of the target lesion using only Presillion or Presillion plus Stent Systems.

[2] Device success - attainment of <50% final residual stenosis of the target lesion using any percutaneous method.

[3] Procedural success - attainment of <50% residual stenosis of the target lesion and no in-hospital death, MI or TLR.

Table 4: Effectiveness and Safety Results through 270 Days

	PRESILLION™ / PRESILLION™ *PLUS* (N=278 PATIENTS N=281 LESIONS)	[95% CI]
PRIMARY ENDPOINT		
TVF-Free at 270 Days	91.3%	[88.0%,94.6%]
EFFECTIVENESS MEASURES		
Lesion Success	100.0% (281/281)	[98.7%,100.0%]
Device Success	98.2% (276/281)	[95.9%,99.4%]
Procedure Success	97.8% (272/278)	[95.4%,99.2%]
TVF-Free at 30 Days	97.5%	[95.6%,99.3%]
Clinically Driven TLR-Free at 30 Days	98.9%	[97.7%,100.0%]
Clinically Driven TVR-Free at 30 Days	98.9%	[97.7%,100.0%]
Clinically Driven TLR-Free at 270 Days	94.9%	[92.3%,97.5%]
Clinically Driven TVR-Free at 270 Days	93.5%	[90.5%,96.4%]
SAFETY MEASURES		
TVF to 30 Days	2.5% (7/277)	[1.0%,5.1%]
All Death to 30 Days	0.4% (1/277)	[0.0%,2.0%]
Target Vessel MI to 30 Days	2.5% (7/277)	[1.0%,5.1%]
TVF to 270 Days	8.7% (24/276)	%,12.7%]
TLF to 270 Days	7.6% (21/276)	[4.8%,11.4%]
All Death to 270 Days	1.4% (4/276)	[0.4%,3.7%]
Target Vessel MI to 270 days	3.3% (9/276)	[1.5%,6.1%]
Stent Thrombosis at Discharge	0.7% (2/278)	[0.1%, 2.6%]
Stent Thrombosis to 270 Days (ARC Definite/Probable) • Acute (0-1 days) • Sub acute (2-30 days)	1.1% (3/276) 0.4% (1/278) 0.7% (2/277)	[0.2%,3.1%]
Bleeding Complications at Discharge	0.0% (0/278)	[0.0%,1.3%]
Vascular Complications at Discharge	1.4% (4/278)	[0.4%,3.6%]

Target Vessel Failure – Cardiac death, target vessel myocardial infarction (Q Wave and non-Q-wave), or clinically driven target vessel revascularization (TVR) by percutaneous or surgical methods.
Target Vessel Revascularization – Any percutaneous intervention of surgical bypass of any segment of the target vessel.
Target Lesion Revascularization – Any percutaneous intervention of the target lesion or bypass surgery of the target vessel performed for restenosis or other complication of the target lesion.
Stent Thrombosis – Thrombus or closure within the stented vessel. Acute (0 – 24 hours post stent implantation), Subacute (>24 hours – 30 days post stent implantation), or late (30 days – 1 year post stent implantation).
Bleeding complication – A procedure-related hemorrhagic event that requires a transfusion and/or surgical intervention
Vascular complication – May include the following: Pseudoaneurysm, Arteriovenous fistula (AVF), Peripheral ischemia/nerve injury, Vascular event requiring transfusion or surgical repair.
Lesion success - the attainment of <50% final residual stenosis of the target lesion using only Presillion or Presillion *plus* Stent Systems.

Device success - the attainment of <50% final residual stenosis of the target lesion using any percutaneous method.
Procedural success - Attainment of <50% residual stenosis of the target lesion and no in-hospital death, MI or TLR.
ARC defined Definite Stent Thrombosis - is considered either angiographic confirmed or pathologic confirmed
Probable Stent Thrombosis - is considered to have occurred in the following cases:

a. Any unexplained death within the first 30 days
b. Irrespective of the time after the index procedure any myocardial infarction (MI) in the absence of any obvious cause which is related to documented acute ischemia in the territory of the implanted stent without angiographic confirmation of stent thrombosis

7.1.5 Gender-based Analysis of the PIONIR Study

Background

Cardiovascular disease is the leading cause of death for both women and men in the U.S. and coronary artery disease is a major cause of morbidity and mortality in women. It is estimated that the prevalence of coronary artery disease in the United States is 9.1% (9,200,000) in males and 7.0% (8,400,000) in females for adults at least 20 years old according to the American Heart Association 2010 Update.[4] However, it is estimated that only 36% of annual PCIs are performed in women.[5] In PCI clinical trials, women represent only 25-35% of the enrolled populations, and there are relatively little gender-specific data. The disproportionate enrollment distribution in these trials may be partly attributable to gender differences in symptoms and pathophysiology,[6] which may lead to under-diagnosis and under-referral of female patients with CAD. Women tend to have worse clinical outcomes compared to men, most likely due to their higher baseline risk profile and more complex angiographic characteristics. [7, 8, 9]

Gender-based analysis

Medinol performed a post hoc evaluation of the PIONIR clinical study for possible sex-based differences in baseline characteristics and clinical outcomes. The PIONIR study was not designed nor powered to study safety and effectiveness differences between sexes, so this analysis is considered exploratory without definitive conclusions.

In the PIONIR study, 66/278 (23.7%) subjects were female and 212/278 (76.3%) were male. In comparison, the prevalence of coronary artery disease (CAD) is estimated at 9.2 million in males and 8.4 million in females for adults age 20 and older in the United States (i.e. the CAD population is estimated to be 52.2% males and 47.7% females).

The disproportionate enrollment distribution in the PIONIR study may be partly attributable to the fact that women have always been underrepresented in clinical trials of coronary interventions. In studies of PCI published between 1990 and 2005, women represented only 15% to 38% (mean = 29.0% women, n = 86,137) of the patient population[6].

Women are also underrepresented in contemporary studies of coronary stenting. Our review of the literature identified only 7 studies with sex-stratified data, with the inclusion of women ranging from 20% to 28% (mean = 25.1% women; n= 2,954).[10, 11, 12, 13, 14, 15, 16]

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With the inclusion of 23.7% women, our PIONIR trial of the Presillion™ *plus* Stent System is representative of contemporary studies.

Table 5 and Table 6 display baseline demographics and angiographic characteristics, respectively.

Table 5: Baseline demographics by gender

	Male (N=212)	Female (N=66)	Difference [95% CI]	P-value
Age (years)	64.3±10.2	69.0±11.0	-4.7[-7.6,-1.7]	0.002
Current smokers	24.1%	22.7%	1.3%[-10.3%,13.0%]	<.001
Hypercholesterolemia	75.8%	77.3%	-1.4%[-13.1%,10.2%]	0.870
Hypertension	69.3 %	81.8%	-12.5%[-23.7%,-1.3%]	0.058
Previous MI	28.3%	26.2%	2.1%[-10.1%,14.4%]	0.874
Diabetes	19.8%	22.7%	-2.9%[-14.4%,8.5%]	0.604
Diet controlled	4.7%	1.5%	3.2%[-0.9%,7.3%]	0.468
Oral Hypoglycemics	10.4%	18.2%	-7.8%[-18.0%,2.4%]	0.130
Insulin	4.7%	3.0%	1.7%[-3.3%,6.7%]	0.737

Table 6: Angiographic characteristics by gender

Measure	Male (N=212)	Female (N=66)	Difference [95% CI]	P-value
Vessel Location				0.237
LAD	35.2% (75/213)	38.8% (26/67)	-3.6%[-16.9%,9.7%]	
LCX	29.1% (62/213)	31.3% (21/67)	-2.2%[-14.9%,10.4%]	
RCA	35.7% (76/213)	28.4% (19/67)	7.3%[-5.2%,19.9%]	
LCMA	0.0% (0/213)	1.5% (1/67)	-1.5%[-4.4%,1.4%]	
Length				0.805
1 - 10 mm	54.9% (117/213)	50.7% (34/67)	4.2%[-9.5%,17.9%]	
10 - 20 mm	40.4% (86/213)	43.3% (29/67)	-2.9%[-16.5%,10.7%]	
> 20 mm	4.7% (10/213)	6.0% (4/67)	-1.3%[-7.6%,5.1%]	
Thrombus	0.9% (2/213)	0.0% (0/67)	0.9%[-0.4%,2.2%]	1.000
Calcification				0.003
Mild	82.2% (175/213)	71.6% (48/67)	10.5%[-1.4%,22.5%]	
Moderate	13.6% (29/213)	11.9% (8/67)	1.7%[-7.4%,10.7%]	
Severe	4.2% (9/213)	16.4% (11/67)	-12.2%[-21.5%,-2.9%]	

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In the post-hoc analysis conducted on the intention-to-treat population, the only significant sex difference observed was a lower rate of target vessel myocardial infarction in women at the 270-day follow-up (1.9% vs 7.6%, p = 0.038). Although not significant (p = 0.057), the rate of cardiac death at 180-day and 270- day follow-up was higher in women (3.3%) than men (0.0%). Due to the modest sample size of this study, this analysis and any interpretation are limited.

Table 7 below displays effectiveness and safety results by gender.

Table 7: Effectiveness and Safety Results by Gender

	MALE (N=212)	FEMALE (N=66)
PRIMARY ENDPOINT		
TVF-Free at 270 Days	92.4%	87.9%
EFFECTIVENESS MEASURES		
Lesion Success	100.0% (214/214)	100.0% (67/67)
Device Success	98.1% (210/214)	98.5% (66/67)
Procedure Success	98.6% (209/212)	95.5% (63/66)
TVF-Free at 30 Days	98.1%	95.5%
Clinically Driven TLR-Free at 30 Days	99.1%	98.5%
Clinically Driven TVR-Free at 30 Days	99.1%	98.5%
Clinically Driven TLR-Free at 270 Days	94.8%	95.4%
Clinically Driven TVR-Free at 270 Days	93.8%	92.3%
SAFETY MEASURES		
TVF to 30 Days	1.9% (4/211)	4.5% (3/66)
All Death to 30 Days	0.0% (0/211)	1.5% (1/66)
Target Vessel MI to 30 Days	1.9% (4/211)	4.5% (3/66)
TVF to 270 Days	7.6% (16/210)	12.1% (8/66)
All Death to 270 Days	1.0% (2/210)	3.0% (2/66)
Target Vessel MI to 270 Days	1.9% (4/210)	7.6% (5/66)
Stent Thrombosis to 270 Days	1.0% (2/210)	1.5% (1/66)
Bleeding Complications at Discharge	0.0% (0/212)	0.0% (0/66)
Vascular Complications at Discharge	1.9% (4/212)	0.0% (0/66)

7.1.6 Conclusion

The 9-month results of the PIONIR study demonstrate Presillion™/ Presillion™ *plus* CoCr Coronary Stent on RX Systems to be safe and effective in the treatment of de novo stenotic lesions in native coronary arteries, when compared to a performance goal derived using a meta-analysis of peer-reviewed literature on coronary stenting with bare metal stents.

7.2 The BLAST Study

7.2.1 Study Overview

The BLAST is a Phase II, randomized, multi-center, prospective, double blind clinical study of the Presillion stent System in combination with Liposomal Alendronate compared to the Presillion Stent System alone in treatment of de novo stenotic lesions in native coronary arteries in a population undergoing PCI. The data from the Presillion-only treatment arm provide supportive information regarding the safety and effectiveness of the Presillion stent.

The primary efficacy endpoint of this study was the 180 days in-stent late lumen loss, as measured by QCA.

An independent Clinical Events Committee adjudicated all SAEs and endpoint AEs.

Summary of the BLAST Study

Study Type	• Prospective • Multi-center study (n=11), performed in Israel • Double blind • Randomized, 3 arms on 1:1:1 basis: o High LA dose + Presillion Stent System o Low LA dose + Presillion Stent System o Placebo IV saline infusion + Presillion Stent System
Number of patients	• Total: 226 • Placebo group: 57
Lesion criteria	Up to 2 de novo stenotic lesions in native coronary arteries (length ≤ 30mm) with a reference vessel diameter of 2.50mm to 3.50mm
Anti-platelet therapy	• Aspirin indefinitely • Clopidogrel for a minimum of 1 month
Follow up	• Clinical follow up at 30 days • Clinical and angiographic (stent) follow up at baseline and 180 days, including Quantitative Coronary Angiography (QCA). • IVUS at baseline at 180 days for pre-specified patients. • Yearly contact through 1-5 years
Sponsor	BIOrest Ltd

7.2.2 Patient Characteristics

	% of Number of patients (N=57)
Age (years)	58.1±8.2
Male	87.7%
Current smokers	42.6%
Hypercholesterolemia	75.4%
Hypertension	66.7%
Previous MI	30.4%
Diabetes • Diet controlled • Oral Hypoglycemics • Insulin	38.6% 22.7% 68.2% 9.1%

7.2.3 Effectiveness and Safety – Results

180 days Data:

The mean (±SD) of in-stent late lumen loss at 180 days for the 57 per-protocol (PP) placebo arm patients was 0.86mm (± 0.60mm).

The overall MACE rate at 180 days for the placebo group was 25.0% (14/56) with 19.65% (11/56) MIs (all being target vessel non ST elevation MIs) and 7.1% (4/56) clinically driven TLR events. (A patient may have experienced more than one such event). There were no deaths or emergent CABG events reported through 180 days.

The overall rate of TLF at 180 days was 25.0% (14/56) as was the overall rate of TVF. There was only one (1.8%) late stent thrombosis event through 180 days of follow-up in the placebo group.

The rate of peri-procedural TV-MI in the BLAST study was 17.5% compared to a rate of 2.2% in the PIONIR study. The difference in these rates is largely attributable to differences in definitions utilized in the two studies. The PIONIR study used the historical WHO definition based on total CK, whereas the BLAST study used the ARC definition utilizing levels of troponin, a more sensitive biomarker. When the events in the PIONIR study are adjudicated against the ARC definition, the resulting rate is 12.6%. Additionally, when patient and lesion characteristics are considered, the BLAST patient study enrolled a more complex patient population compared to the PIONIR study, with higher rates of unstable angina and diabetes and more complex lesion characteristics. Given these differences between studies, the difference in MI rates between studies did not raise a safety concern.

The principal effectiveness and safety results are shown in Table 8 below, which continues on the subsequent page:

Table 8: Principal Effectiveness and Safety Results

	PLACEBO (N=57)	**[95% CI]**
EFFECTIVENESS MEASURES		
Acute Success		
Lesion Success	100.0% (65/65)	[94.5%,100.0%]
Procedure Success	82.5% (47/57)	[70.1%,91.3%]
Treatment Success	82.5% (47/57)	[70.1%,91.3%]
Follow-up (6-month)		
Follow-up In-Stent Minimal Lumen Diameter (MLD, in mm)		
Mean±SD (N)	1.77±0.80 (57)	[1.55,1.98]
Range (min,max)	(0.00,3.41)	
Median	1.81	
Follow-up In-Stent Percent Diameter Stenosis (% DS)		
Mean±SD (N)	36.64±24.88 (57)	[30.04,43.24]
Range (min,max)	(-6.40,100.00)	
Median	35.40	

	PLACEBO (N=57)	[95% CI]
Follow-up In-Segment Minimal Lumen Diameter (MLD, in mm)		
Mean±SD (N)	1.68±0.72 (57)	[1.49,1.87]
Range (min,max)	(0.00,3.00)	
Median	1.61	
Follow-up In-Segment Percent Diameter Stenosis (% DS)		
Mean±SD (N)	39.84±21.68 (57)	[34.08,45.59]
Range (min,max)	(3.81,100.00)	
Median	35.58	
Late Loss In-Stent (mm)		
Mean±SD (N)	0.86±0.60 (57)	[0.70,1.02]
Range (min,max)	(-0.08,2.24)	
Median	0.83	
Late Loss In-Segment (mm)		
Mean±SD (N)	0.68±0.58 (57)	[0.53,0.84]
Range (min,max)	(-0.37,1.81)	
Median	0.62	
In-Stent Binary Restenosis	26.3% (15/57)	[15.5%,39.7%]
In-Segment Binary Restenosis	26.3% (15/57)	[15.5%,39.7%]
SAFETY MEASURES		
In-Hospital MACE	17.5% (10/57)	[8.7%,29.9%]
Out-of-Hospital MACE to 180 Days	7.1% (4/56)	[2.0%,17.3%]
MACE to 180 days	25.0% (14/56)	[14.4%,38.4%]
Type I MI (STEMI, NSTEMI)*	19.6% (11/56)	[10.2%,32.4%]
Type II MI (Q-Wave, Non-Q-Wave)*	19.6% (11/56)	[10.2%,32.4%]
Cardiac Death or MI	19.6% (11/56)	[10.2%,32.4%]
Clinically-Driven Target Lesion Revascularization (TLR)	7.1% (4/56)	[2.0%,17.3%]
Target Vessel Failure (TVF)	25.0% (14/56)	[14.4%,38.4%]
Target Lesion Failure (TLF)	25.0% (14/56)	[14.4%,38.4%]
Bleeding Complications	0.0% (0/56)	[0.0%,6.4%]
Vascular Complications	0.0% (0/56)	[0.0%,6.4%]
Stent Thrombosis	1.8% (1/56)	[0.0%,9.6%]

* Each MI was categorized for both groups.

7.2.4 Conclusions

The outcomes of the Presillion-only cohort (57 patients) in the BLAST trial at 180 days post-procedure are presented above. The Quantitative Angiographic Analysis and clinical outcomes are generally consistent with the outcomes of the PIONIR study.

7.3 The Belgian Registry

7.3.1 Study Overview

This non-randomized, multi-center, single-arm registry was initiated with the objective of capturing 30-day outcomes. At a later stage, the follow up period was prolonged per the Belgian health authority's request to include an additional data point (as close as possible to, but after, the 6-month post procedure date).

The main objective of this study is to evaluate the safety of Presillion Stent System in the treatment of de novo stenotic lesions in native coronary arteries.

The primary safety measure is a composite of MACE [includes cardiac death, MI (Q-wave and Non-Q-wave) and clinically driven Target Lesion Revascularization (TLR)] at 30 days and 180 days post procedure.

Summary of the Belgian Registry

Study Type	• Multi center (n=8), performed in 7 centers in Belgium and 1 center in Luxemburg • Single arm Direct stenting (stent implantation without balloon pre-dilatation) was allowed to most closely address daily routine clinical practice.
Number of patients	101 patients enrolled for the study • 30-day follow up: 101 • 6-month to 1-year follow up: 89
Lesion criteria	Up to two (2) de novo native coronary artery lesions with a maximum lesion length of 30mm in a maximum of two major coronary arteries with reference vessel diameter ≥ 2.5mm and ≤ 4.0mm by visual estimation
Anti-platelet therapy	• Aspirin, indefinitely • Clopidogrel or Ticlopidine, for a minimum of 1 month
Follow up	• 30 days • Prolonged to 180 days, up to 1 year
Sponsor	Cordis, a J&J company

7.3.2 Patient Characteristics

	% of Number of patients (N=101)
Age, mean (years)	66.1±10.6
Male	69.3%
History of smoking	64.4%
Hypercholesterolemia	76.2%
Previous MI	24.8%
Hypertension	71.3%
Diabetes	1.0%

7.3.3 Principal Safety and Effectiveness Results

Table 9: 1 month follow up (N=101)

	RATE AT 1 MONTH
PRIMARY ENDPOINT	
MACE (cardiac death, myocardial infarction, target lesion revascularization)	0%
Secondary endpoints	
In-hospital MACE	0%
Clinically-driven Target Lesion Revascularization	0%
Clinically-driven Target Vessel Revascularization	0.99%
Target Vessel Failure	0%
Myocardial Infarction	0%
Major bleeding	0%
Stroke	0%
Procedural success	99.0%
Lesion success (n=111)	100%
Device success (n=111)	97.3%

Table 10: 180 days or beyond follow up (N=89)

ENDPOINTS	RATE AT 180 DAYS
MACCE (death, stroke, MI, CABG, TVR, non TVR)	7.9%
Cardiac death	1.1%
Non-cardiac death	0%
Non-fatal QMI	0%
CABG	0%
Ischemia driven TVR	4.5%
Ischemia driven non TVR	1.1%
Stroke	1.1%
Stent thrombosis	1.1%
TVF (cardiac death, MI, TVR)	5.6%

7.3.4 Conclusion

The information gathered in this registry indicates that the safety profile of the Presillion stent in the treatment of de novo coronary artery stenosis is generally consistent with the results of the PIONIR study.

8. Patient Selection and Treatment

8.1 Individualization of Treatment

The risks and benefits should be considered for each patient before use of Presillion™ *plus* CoCr Coronary Stent on RX System . Patient selection factors to be assessed should include a judgment regarding risk of antiplatelet therapy.

Special consideration should be given to those patients with recently active gastritis or peptic ulcer disease.

Co-morbidities that increase the risk of poor initial results or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure, and severe obesity) should be reviewed.

Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3mm, intra-procedural thrombus, and dissection following stent implantation.

9. How Supplied

- **STERILE.** This device is sterilized with Ethylene Oxide (ETO) gas and is nonpyrogenic. **For single use only. Do not re-sterilize or re-use. Do not use the device if the package is opened or damaged.**
- Use prior to the expiration date ("Use By" date).
- **CONTENTS:** One (1) Presillion *plus* Stent System
- **STORAGE.** Store in a cool, dark, dry place.

10. Operator's Manual

10.1 Inspection Prior to Use

Before opening, carefully inspect the stent delivery system package for damage to the sterile barrier. **Do not use the device if there is any damage to the packaging.**
Prior to using the device, carefully remove the system from the package and inspect for bends, kinks, and other damage.
Verify that the stent is located between the radiopaque markers.

Do not use if any defects are noted.

10.2 Materials Required

Quantity	Material
N/A	Appropriate guiding catheter(s)
2-3	10-20 cc syringes
1,000 u / 500 cc	Sterile Heparinized Normal Saline (HepNS)
1	0.14" (0.36mm) diameter guidewire
1	Introducer sheath
1	Rotating hemostatic valve with an appropriate internal diameter
N/A	Contrast diluted 1:1 with normal saline
1	Inflation device
1	Three-way stopcock
N/A	Appropriate anticoagulation and anti-platelet drugs

10.3 Preparation

Carefully remove the shipping mandrel (stainless steel rod) from the tip (distal end of system).

CAUTION: If unusual resistance is felt during mandrel removal, do not use this product.

10.3.1 Catheter Rinse

Rinse the catheter with sterile heparinized saline solution.

10.3.2 Stent System Guidewire Lumen Flush

Flush the stent system guidewire lumen with HepNS using flushing needle.

CAUTION: AVOID manipulation of stent during flushing of guidewire lumen, as this may disrupt the placement of the stent on the balloon.

10.3.3 Delivery System Preparation

1. Prepare inflation device with diluted contrast medium.
2. Attach inflation device to stopcock; attach to hub (balloon inflation port).
3. Open stopcock to stent delivery system.
4. Apply negative pressure for 30 seconds, release inflation device, and leave on neutral for contrast fill.
5. Close the stopcock to the delivery system; purge the inflation device/syringe of all air.
   CAUTION: If air is seen in the shaft, repeat Delivery System Preparation to prevent uneven stent expansion.

10.4 Delivery Procedure

1. Prepare vascular access site according to standard practice.
2. Pre-dilate lesion site with PTCA catheter.
3. Maintain neutral pressure on inflation device. Open rotating hemostatic valve as widely as possible.
4. Backload delivery system onto proximal portion of guidewire while maintaining guidewire position across target lesion.
5. Advance the stent delivery system over guidewire to target lesion. Utilize radiopaque balloon markers to position stent across lesion; perform angiography to confirm stent position.

CAUTION: While introducing the delivery system into the vessel, do not induce negative pressure on the delivery system. This may cause dislodgment of the stent from the balloon.

NOTE: Should any resistance be felt at any time during either lesion access pre-stent implantation or removal of the stent delivery system post-stent implantation, the entire system should be removed as a single unit. See section 5.4 *Stent/System Removal - Precautions* for specific stent delivery system removal instructions.

10.5 Deployment Procedure

1. Before deployment, reconfirm the correct position of the stent relative to the target lesion via the radiopaque balloon markers.
2. Under fluoroscopic visualization, inflate the balloon to at least the nominal pressure to deploy the stent, but do not exceed the labeled rated burst pressure.

   NOTE: Refer to product labeling and Table 11 Compliance Chart for in-vitro stent inner diameter, nominal pressure, and RBP. Presillion *plus* Stent System may be inflated beyond nominal pressure, without repositioning, up to rated burst pressure, to assure complete apposition of the stent to the artery wall.
3. Maintain inflation pressure for 15-30 seconds for full expansion of the stent. Optimal expansion requires the stent to be in full contact with the artery wall, with the stent internal diameter matching the size of the reference vessel diameter. Stent wall contact should be verified through routine angiography or intravascular ultrasound.

Table 11: Presillion *plus* Stent System Compliance Chart

PRESSURE (ATM)	LABELED DIAMETER (MM)					
	2.50	**2.75**	**3.00**	**3.50**	**4.00**	
9	2.31	2.57	2.82	3.26	3.75	**Diameter at Nominal Pressure**
10	2.37	2.63	2.88	3.34	3.83	
11	2.44	2.69	2.94	3.42	3.92	
12	**2.50**	**2.75**	**3.00**	**3.50**	**4.00**	
13	2.54	2.78	3.03	3.54	4.04	
14	2.58	2.82	3.07	3.59	4.09	**Diameter at RBP**
15	2.63	2.85	3.10	3.63	4.13	
16	2.67	2.88	3.14	3.67	4.17	
17	2.71	2.91	3.17	3.72	4.22	
18	2.75	2.95	3.21	3.76	4.26	
19	2.78	2.97	3.23	3.79	4.30	
20	2.81	3.00	3.26	3.83	4.33	

The compliance data are based on in vitro bench testing at 37°C.

NOTE: Balloon pressures should be monitored during inflation. Do not exceed rated burst pressure as indicated on product label as this may result in a ruptured balloon with possible intimal damage and dissection.

4. Deflate the balloon by pulling negative pressure on the inflation device for 30 seconds
5. Confirm adequate stent expansion by angiographic injection through the guiding catheter.

NOTE: All efforts should be taken to assure that the stent is not under dilated. If the deployed stent size is still inadequate with respect to vessel diameter, or if full contact with the vessel wall is not achieved, a larger balloon may be used to expand the stent further. The stent may be further expanded using a low profile, high pressure, non-compliant balloon catheter. If this is required, the stented segment should be re-crossed carefully with a prolapsed guidewire to avoid dislodging the stent. The balloon should be centered within the stent and should not extend outside of the stented region.

CAUTION: Do not dilate the stent beyond the following limits:

Nominal Stent Diameter (mm)	Dilatation Limits (mm)
2.50 mm	3.00 mm
2.75 mm	3.50 mm
3.00 mm	3.75 mm
3.50 mm	4.25 mm
4.00 mm	4.75 mm

10.6 Removal Procedure

1. Ensure the delivery system is fully deflated.
2. While maintaining guidewire position and negative pressure on the inflation device, withdraw the stent delivery system.

   NOTE: Should unusual resistance be felt at any time during either lesion access or removal of the stent delivery system pre-stent implantation, the entire system should be removed as a single unit. See section 5.4 *Stent/System Removal - Precautions* for specific stent delivery system removal instructions.
3. During withdrawal of the delivery system, hold saline-soaked gauze around the exposed catheter shaft and pull the catheter through the gauze to remove blood or any other residues.
4. Repeat angiography to visually assess the vessel and the stented area. If an adequate expansion has not been obtained, exchange back to the original delivery catheter or exchange to another balloon catheter of appropriate balloon diameter to achieve proper stent apposition to the vessel wall.
5. Final internal stent diameter should match reference vessel. **Assure that the stent is not underdilated**.

11. Disclaimer of Warranty and Limitation of Remedy

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A PATIENT`S GUIDE TO CORONARY ARTERY DISEASE

AND YOUR PRESILLION™ *PLUS* CoCr CORONARY STENT ON RX SYSTEM

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ABOUT THIS BOOKLET

Your doctor has prescribed a Presillion™ Stent to help manage your coronary artery disease (CAD). The Presillion™ *plus* CoCr Coronary Stent on RX System will be implanted into your coronary vessel following the angioplasty procedure. This stent will act as miniature scaffolding to help your vessel maintain its shape, strength and integrity.

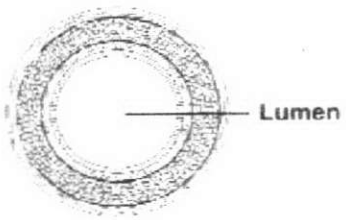
The information in this booklet will help to prepare you for your hospital stay, the stenting procedure and your recovery. It describes the Presillion™ stent, how the Presillion™ stent is implanted and what you can do to facilitate your recovery.

If you have any questions about the Presillion stent or the stenting procedure after you read this booklet, be sure to ask your doctor.

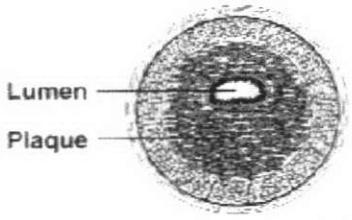
If you need additional information about the Presillion™ stent, please call Medinol's Customer Service at **+1-617-878-2024**.

WHAT IS CORONARY ARTERY DISEASE (CAD)

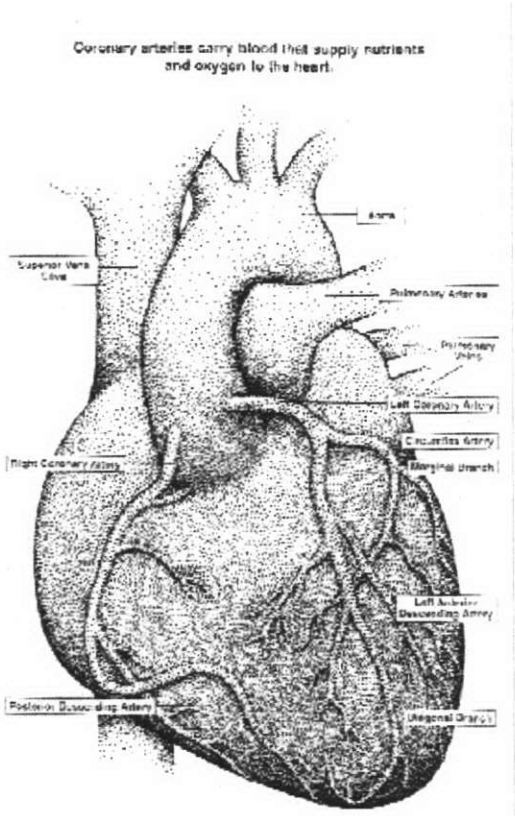
Coronary Artery Disease (CAD) affects the coronary arteries that surround the heart. These coronary arteries supply blood with oxygen to the heart muscle to allow it to function properly. CAD occurs when the inner walls of the coronary arteries thicken due to plaque, a buildup of cholesterol, fatty deposits, calcium, and other elements carried in the blood. As the plaque develops, the vessel narrows. When the vessel narrows, blood flow through the lumen, the center of the vessel, is restricted, so less oxygen and other nutrients reach the heart muscle. This condition, known as atherosclerosis, may lead to chest pain (angina pectoris) or a heart attack (myocardial infarction).



Healthy coronary vessel



Occluded (narrowed) coronary vessel



Coronary Artery Disease Risk Factors

The likelihood of having CAD is greater if you:

- Are male
- Have high blood pressure
- Have diabetes
- Have a high level of blood cholesterol
- Smoke cigarettes
- Are overweight
- Have a close relative with CAD

Symptoms of Coronary Artery Disease

Symptoms of CAD differ from person to person; however, typical symptoms include: pressure, tightness or pain in the chest, arm, back, shoulder, neck or jaws. Heartburn, nausea, vomiting, shortness of breath and heavy sweating may also occur.

Women are more likely than men to have atypical chest pain which may be fleeting or sharp and noticed in the abdomen, back, or arm and are somewhat more likely than men to experience other warning signs of a heart attack, including nausea and back or jaw pain.

Sometimes a heart attack occurs without any apparent signs or symptoms.

Diagnosis of Coronary Artery Disease

When making a diagnosis, your doctor will ask about your symptoms, medical history, and risk factors. Based on this information, your doctor may ask you to undergo a series of tests to see how healthy your arteries are.

Doctors may use various tests to diagnose CAD. An ECG (or EKG), or electrocardiogram, measures your heart's electrical activity and may show whether parts of your heart muscle have been damaged by heart attack caused by CAD. A stress test records your heart's electrical activity while you are exercising and may tell your doctor whether part of your heart muscle is damaged. The most accurate way to diagnose CAD is to perform a coronary angiogram. This is done by injecting a contrast dye into the coronary arteries so they can be seen on an x-ray screen. The x-ray will show if artery narrowing has occurred.

Treatment of Coronary Artery Disease

To determine what treatment is right for you, your cardiologist will take a number of factors into consideration, including your overall medical condition, your cardiovascular condition, the condition of your coronary arteries, your age, your health history, and the results of the previously mentioned series of tests.

Coronary artery disease may be managed through a combination of changes in lifestyle and physical activity, diet, and medical treatment. The therapy your doctor recommends will depend on the condition and severity of the disease. Medical treatments of the blockage may include medications, angioplasty (widening the opening with a balloon), stent implantation or coronary artery bypass surgery.

Angioplasty

Angioplasty, also known as Percutaneous Transluminal Coronary Angioplasty (PTCA), is a minimally invasive treatment performed in the hospital to open the blocked coronary arteries. A thin tube known as a catheter is inserted through the groin or wrist and is then threaded through a major blood vessel to the site of the blockage. A small balloon, located on the tip of the catheter, is then expanded to reduce the blockage. PTCA can be performed with a balloon alone, or can involve the placement of a coronary stent (see *Coronary Artery Stents*, below).

Coronary Artery Stents

Stenting is a common procedure in which a stent is implanted in a blocked vessel.
Coronary artery stents are devices that can help to reduce the risk of re-narrowing of the treated artery following an angioplasty procedure. Stents are small steel tubes that are implanted into a vessel and expanded to fit the size, shape and bend of the vessel wall, propping it open to help prevent further blockages.

During the stenting procedure, the stent is mounted onto a tiny balloon that is opened inside of a coronary artery to push back plaque and to restore blood flow. After the plaque is compressed against the arterial wall, the stent is fully expanded into position, acting as miniature "scaffolding" for the artery. The balloon is then deflated and removed, and the

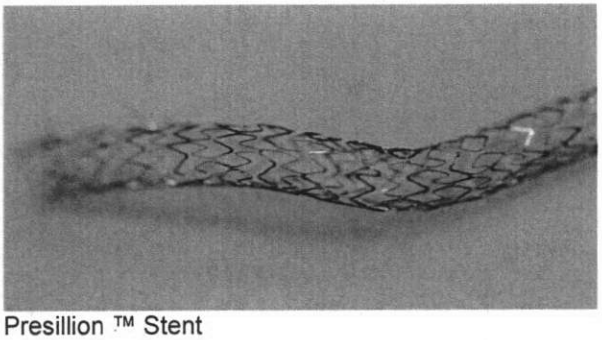
stent is left behind in the patient's coronary artery to help keep the blood vessel open. For some patients it may be necessary to place more than one stent in the coronary artery.

Some of the factors that could help determine whether you are a good candidate for stenting are:

- Your overall health
- The size of the vessel and number of coronary arteries involved
- The location of the blocked coronary artery
- How easily the blockage can be reached by angioplasty
- Your recent coronary health history – including heart attacks

THE PRESILLION™ STENT

The Presillion ™ stent is a small, mesh, metal tube. The stent is secured to a balloon at the end of a delivery catheter that delivers it to the location where it will be implanted. When the balloon is inflated, the stent expands until it has made full contact with the vessel wall, adapting to fit the shape, size, and bends of the vessel. Once in place, the stent will remain in your artery. Over time, the lining of the artery wall will grow around the stent as the stent continues to support the vessel.



Presillion ™ Stent

Clinical Data

The PIONIR Study was the main clinical study to investigate the Presillion *plus* Stent. In this study, 278 patients received the Presillion *plus* Stent. After 9 months, the Presillion *plus* Stent was as effective as other bare metal stents at preventing major adverse cardiac events (need for a repeat procedure, heart attack and death; 12.7% for the Presillion plus vs. 16.46% in a combined analysis of other approved coronary bare metal stents).

Who Should Not receive the Presillion™ plus *CoCr Coronary Stent on RX System*

Coronary artery stenting is generally contraindicated for:

- Patients for whom blood thinning medications (anticoagulants) and/or antiplatelet is contraindicated
- Patients judged to have a lesion which prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery system.

Potential Risks of Treatment with the Presillion™ plus CoCr Coronary Stent on RX System

Use of the Presillion™ *plus* CoCr Coronary Stent on RX System carries the risks associated with all coronary stent placements in native coronary arteries. The following complications may occur during or after placement of a coronary stent in your body:

- Abrupt vessel closure – sudden blockage or closure of the vessel caused by stent
- Allergic / drug reaction - to contrast dye, stent material (Cobalt Chromium) or medication
- Aneurysm / Pseudoaneurysm – weakening of a portion of the wall of the blood vessel
- Arrhythmias, ventricular fibrillation – irregular heart beat
- Cardiac tamponade – bleeding around the heart
- Coronary artery spasm
- Death
- Dissection – ruptured or torn artery
- Emboli – air, pieces of devices or fragments of clots blocking the blood vessel
- Emergency CABG – emergency bypass surgery
- Failure to deliver the stent to the intended site
- Fever
- Fistulization - an abnormal connection between two vessels that normally do not connect
- Hemorrhage (bleeding), or hematoma
- Hypotension / Hypertension – decreased or increased blood pressure
- Infection and pain at the insertion site groin or arm
- Myocardial infarction – heart attack
- Myocardial ischemia, Angina - chest pain due to reduced oxygen to the heart
- Occlusion / restenosis of the stented artery section– re-narrowing of the treated artery
- Perforation – tearing, puncture or rupture of the heart artery
- Renal failure
- Repeat percutaneous intervention – repeat procedure to reopen the heart artery
- Stent compression – damage to the stent
- Stent misplacement / migration / embolization – movement of the stent from where it was placed
- Stroke
- Thrombosis (acute, subacute or late) – blood clot in the heart artery, in different times from stent implantation

BEFORE THE PROCEDURE

Instructions

Your doctor will instruct you on how to prepare for the angioplasty and stent implantation procedures prior to being admitted to the hospital. Your doctor may ask you to take aspirin and other prescribed medications for several days before the procedure. This is done to "thin" the blood to prevent blood clots (thrombus) from forming during the stenting procedure. It is important to tell your doctor if you cannot take aspirin or have a history of bleeding problems. Your doctor also needs to know if you are taking any other medications or if you have any drug allergies.

DURING THE PROCEDURE

Your angioplasty procedure and the stent implantation will be performed in a specially equipped area of the hospital called the cardiac catherization laboratory. The PTCA and stent implantation will be performed by an interventional cardiologist, a doctor who specializes in angioplasty and stenting. After the stent is implanted, you will be moved to a cardiology ward for a short period where you can be monitored closely as you begin to recover.

Angioplasty – Opening a Blocked Coronary Vessel

Your doctor will decide which site on your body would be the best place to access one of your arteries – your groin area, wrist, or arm. The selected area will be shaved and cleaned with antiseptic and you will be given a local anesthetic to numb the area.

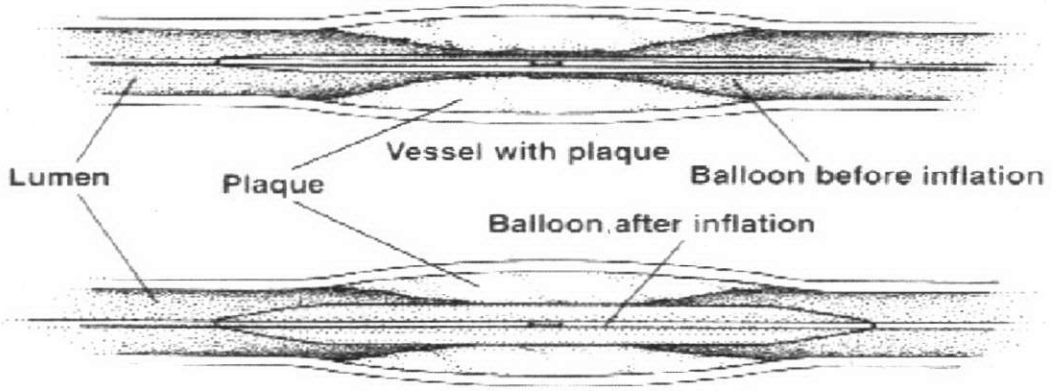
During the procedure, you will have to lie flat on your back and you will remain awake, allowing you to follow your cardiologist's instructions (e.g., "breathe deeply"). Devices will monitor your heart rate and blood pressure.

The procedure will begin with an angiography test to determine the number and exact location of blockages.

To obtain access to the artery, a short smooth catheter, called a sheath, is inserted via the groin or arm.

A thin tube called a guiding catheter is inserted into the sheath and maneuvered up to the heart. The guiding catheter acts as a conduit or pathway to the coronary arteries for subsequent devices (including the stent) and contrast fluid. With the area being observed on an x-ray screen, contrast dye is injected through the guiding catheter and the coronary arteries become visible on the screen. After the exact position of the narrowing has been determined, a small wire is advanced through the artery and past the narrowing.

Then, over this wire, a balloon catheter is advanced and when positioned within the narrowing, the balloon is inflated. By inflating the balloon, the stenosis (blockage) is dilated (opened), and the vessel is widened. Let your doctor know if you are experiencing any pain.

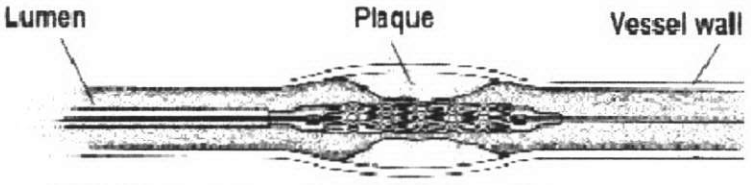


Opening vessel with balloon

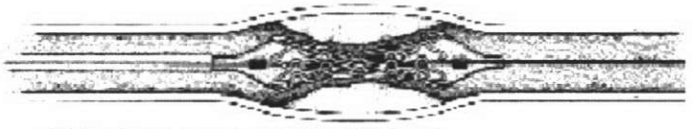
How Is the Stent Implanted

- After the artery is widened, your doctor will pass the stent, mounted on a balloon catheter used as the delivery catheter, into the coronary artery through the same guiding catheter.
- Then, your doctor will carefully position the stent at the place where the blockage was before angioplasty, known as the target site. By using a type of x-ray machine called a fluoroscope, your doctor will be able to see the Presillion™ stent inside the vessel. This helps to position the stent at exactly the right location.
- Once the stent is in place, your doctor will inflate the balloon and expand the stent , using an inflation device and position it to the inner wall of the artery. The stent will shape itself to the size and contours of your vessel and keep the artery open. It is common for patients to feel some mild discomfort when the balloon is inflated because the artery is being stretched
- When the stent is in place, the balloon is deflated and the delivery catheter is removed. The stent will remain in place and continue to keep the artery open.

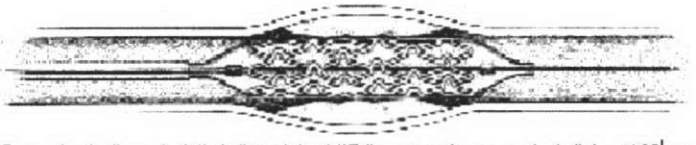
Implanting Stent



NIRflex Stent on delivery catheter before balloon inflation



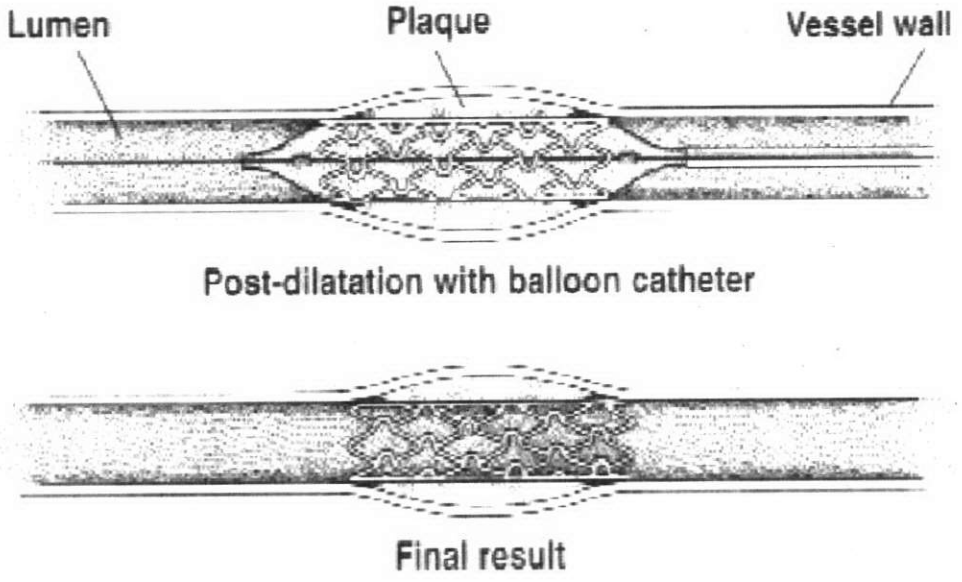
NIRflex Stent expands as balloon is inflated



Once the balloon is fully inflated the NIRflex stent is expanded, fitting the vessel size and contour

- Your doctor may choose to expand the stent further by using another balloon. If required, the balloon catheter is inserted inside the stent and then inflated to allow the stent to make better contact with the vessel wall. This part of the procedure is called post- dilatation.
- The stent achieves full contact with the vessel wall and provides unobstructed blood flow, just like a healthy vessel does. When the stent is flush with the vessel wall physicians call this proper stent apposition. Once in place, the Presillion stent will remain in your artery permanently.

Further Expansion of Stent



AFTER THE PROCEDURE

After the procedure, you may be instructed to lie flat for several hours. You will go to a special care unit where medical staff will monitor your heart rate and blood pressure closely. Before returning to your room, the sheath that was used to enter the vessel may be removed and pressure applied to the puncture site until the bleeding has stopped.

The catheter insertion site may be bruised and sore. If the sheath was inserted into your arm or wrist, it will be removed and the site will be bandaged. If the catheter was inserted into your groin, you may need to lie in bed with your leg straight for several hours. In some cases, your doctor may use a device that seals the small hole in the artery; this may allow you to move around more quickly. The place on your body where the catheter was inserted will be monitored for any changes in color, temperature, or sensation.

Your blood will be frequently tested to monitor and regulate medication levels that control the clotting of your blood.

Taking Care of Yourself at Home

- Contact your doctor or the hospital immediately if you experience pain, bleeding, discomfort, or changes such as severity or frequency in angina symptoms (chest pain).
- Follow your doctor's instructions exactly regarding the use and dosage of medications prescribed.
- Tell your dentist or other medical personnel you are on blood thinners prior to any treatment. Postpone dental work until after your recovery.
- Avoid strenuous exercise unless approved by your doctor.

- Return to normal activities gradually, pacing your return to activity as you feel better. Check with your doctor about strenuous activities.
- Let your doctor know about any changes in lifestyle you make during your recovery period.
- Report side effects from medications immediately. These may include headaches, nausea, vomiting or rash.
- Do not stop taking your medications unless you are asked to stop by the doctor who implanted your stent.
- Keep all follow-up appointments, including laboratory blood testing.

Medications

Your doctor may prescribe a number of medications which thin the blood to prevent blood clots from forming and adhering to the surface of the stent. Patients who take these medications are also required to take blood tests frequently so their blood clotting time can be monitored. Your doctor will let you know when you can stop taking this medication. Until then, it is extremely important to follow your medication regimen. Check with your doctor before taking antacids as they may decrease absorption of aspirin and other medications.

Follow- Up Examinations

You will need to see the doctor who implanted your stent for routine follow-up examinations. During these visits, your doctor will monitor your progress and evaluate your medications, the clinical status of your CAD, and how the stent is working for you.

Magnetic Resonance Imaging (MRI)

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a Presillion™ stent. The technician will need to operate the machine within certain limits.

FREQUENTLY ASKED QUESTIONS

If you are a candidate for stenting to treat coronary artery disease (CAD), you will most likely have a lot of questions to discuss with your doctor. Here are some questions and answers to get you started. Keep in mind that your doctor is your best source of information and advice about CAD and treatment for CAD. Be sure to bring up any additional questions and concerns you may have about CAD with your doctor.

Will I feel the stent? No. You will not feel the stent inside of you.

Can the stent move or rust? Once the stent is opened and presses into the inside wall of your coronary artery, it will remain in place permanently; the stent does not move on its own. Vessel tissue will grow around the stent and hold it in place. It will not rust because it is made of non-corroding metal.

Can I walk through metal detectors with a stent? Yes, without any fear of setting them off. The stent is made of non-magnetic metals.

Why has my doctor recommended stenting? You have heart disease. Most likely your doctor has recommended medication and lifestyle changes that have not been enough to reduce the effects of your clogged arteries. For most patients, the doctor decides that a balloon alone is not enough to keep the coronary artery from narrowing and stent implantation is recommended.

How long should I take my medications? The most important thing that you can do to minimize the risk of stent thrombosis is to take the medications your doctor prescribes. Do not stop taking these medicines until your cardiologist tells you to, even if you are feeling better.

What if I still get pains? If you experience pain, inform your cardiologist or the center where the procedure was performed immediately.

Can I play sports? Yes, but be cautious! Your doctor will tell you what sports you can play and when you can start.

What should I change in my diet? Your doctor may prescribe a low-fat, low-cholesterol diet to help reduce the levels of fat in your blood and reduce your risk.

Will I experience the symptoms of coronary artery disease again, such as chest pain? It is possible that you will experience symptoms again, either because of a new blockage in the treated coronary artery or a new blockage in a different place. If you experience these symptoms, notify your doctor immediately.

How will I know if my artery re-narrows? Although the stents are intended to reduce restenosis, it is still possible for your artery to re-narrow. If this happens, you may experience symptoms similar to those experienced when you first noticed you had coronary artery disease or before your stent procedure. These symptoms may include chest pain or shortness of breath, especially during physical activity. If you experience pain, inform your doctor immediately.

GLOSSARY

Angina Pectoris – Discomfort, pain, tightness or pressure in the chest, usually due to interference with blood flow to the heart muscle and precipitated by excitement or effort. May also cause profuse sweating, nausea, shortness of breath and associated pain in the neck, jaw, back, or arm.

Angiography –An imaging test performed by injecting contrast dye into the coronary arteries so that the vessels can be seen on an x-ray screen. The x-ray will show if any blockages and/or artery narrowing has occurred and if the blocked coronary arteries can be treated with angioplasty or stenting.

Angioplasty – A minimally invasive treatment that uses a balloon to open blocked arterial vessels, also known as percutaneous transluminal coronary angioplasty (PTCA).

Anticoagulant – Medicine such as heparin, which slows or prevents blood from clotting by interfering with blood clotting agents.

Antiplatelet – Medicine such as aspirin, which acts against blood platelets in order to prevent the release of blood clotting agents.

Apposition – Refers to the position of the stent against the vessel wall.

Atherosclerosis – A disease in which the flow of blood to the heart is restricted with plaque deposits (a build-up of cholesterol and other fats, calcium and certain other elements carried in the blood) causing less oxygen and other nutrients to reach the heart muscle. This may lead to chest pain (angina pectoris) or to a heart attack (myocardial infarction).

Catheter – A small thin plastic tube used to provide access to parts of the body, such as into the coronary arteries of the heart or into the bladder.

Clopidogrel – A medicine that thins the blood and helps prevent clot formation.

Coronary – Related to arteries that supply blood to the heart.

Coronary Angiogram – A test that can determine if CAD is present. Contrast dye is injected into the coronary arteries and a fluoroscope allows the doctor to see the narrowed or blocked vessels, a stent, or catheter on an x-ray screen.

Coronary Artery Disease (CAD) – Disease affecting the coronary arteries that surround the heart and supply blood to the heart muscle. CAD occurs when the lumen of the coronary arteries becomes narrowed with plaque deposits (a build–up of cholesterol and other fats, calcium, and other elements carried in the blood).

Coronary Arteries – The arteries that surround the heart and supply blood containing oxygen and nutrients to the heart muscle. Oxygen deprivation to the heart restricts heart function and may lead to chest pain (angina pectoris) or to a heart attack (myocardial infarction).

Coronary Artery Bypass Graft Surgery (CABG) – Open heart or bypass surgery.

ECG – Electrocardiogram. See stress test.

Exercise Electrocardiogram – See Stress test.

Ischemia – A condition that results from reduced oxygen supply to cells, usually due to an obstruction that reduces blood flow.

Lumen – The inner channel of a vessel or tube.

Minimally Invasive- A minimally invasive procedure is any procedure (surgical or otherwise) that is less invasive than an open surgery used for the same purpose.

Myocardial Infarction – Permanent damage to the heart muscle due to the interruption of blood supply to the area, commonly referred to as a heart attack; can occur when blood clots form within the blood vessels.

Magnetic Resonance Imaging (MRI) – A non-invasive way to take pictures of the body. MRI uses powerful magnets and radio waves, unlike x-rays and computed tomography (CT) scans, which use radiation.

Native Lesion- is a coronary artery lesion not previously treated

Percutaneous Transluminal Coronary Angioplasty – See Angioplasty

Plaque – An accumulation or build-up of cells, cellular debris, cholesterol, calcium, fatty deposits, and collagen in a blood vessel that leads to narrowing of the lumen.

Post-Dilatation – After the stent has been expanded, another balloon catheter may be inserted inside the stent and inflated to size the stent more precisely to the normal diameter of the blood vessel.

PTCA – Percutaneous Transluminal Coronary Angioplasty:

Restenosis – Recurrent blockage or narrowing of a previously treated vessel.

Stent – A small, expandable, metal tube that is inserted into a coronary artery to support the blood vessel wall and maintain healthy blood flow through the opened vessel.

Stent Thrombosis- Stent thrombosis is a rare condition that occurs when a blood clot forms on the surface of a stent, raising the risk of blood flow in an artery being reduced or cut off

Stress Test – A test to measure electrical activity in the patient's heart (ECG) while the patient is performing controlled exercise. The results help determine if there is damage to the heart muscle or if blood flow has been restricted to areas of the heart.

Transluminal – Through the lumen which is the inner channel of a vessel.

Vessel – A vein or artery.